

**REMARKS**

**Status of the Claims**

Claims 30, 33, 36, 41-50, 60-69, and 75-85 are pending. Claims 31, 32, 34, 35, 37-40, 51-59, 70-74, and 86-88 have been withdrawn by the Office, as being drawn to non-elected subject matter. Claims 30, 33, 36, 41-50, 60-69, and 75-85, remain rejected as allegedly obvious under 35 U.S.C. §103(a). Office Action, pages 2-9. No claims are amended by this response.

**I. Finality of Office Action is Premature**

Applicants believe the finality of the Office Action is premature. The Office alleges that Applicants' amendment filed April 23, 2003, amending claims 30 and 83-85, necessitated the new grounds of rejection presented in this Office Action, and therefore made the Action final in accordance with MPEP § 706.07(a). *Id.*, page 9. Applicants disagree with the finality of the rejections for the following reasons.

It appears that the Office's new grounds for rejection allege that the newly cited references teach or suggest compositions with a hydrophilic gelling agent present in a concentration of less than 20% by weight, as recited in amended claims 30 and 83-85. *Id.*, pages 2-9. We do not believe these new grounds for rejection were necessitated by the amendment filed April 23, 2003, because the full scope of amended claims 30 and 83-85 was previously searched and considered by the Office in the Office Action dated January 23, 2003. For example, Applicants point out that any new search and consideration of compositions with hydrophilic gelling agent present in a concentration of less than 20% by weight of all claims by the present Office Action would have been encompassed by the search and consideration of gelling agents "ranging up to 20%" recited in claim 41 in the Office Action dated January 23, 2003. Therefore, the

amendment filed April 23, 2003, does not necessitate the new grounds for rejecting claim 30, and claims dependent thereon, because the subject matter therein was already searched and considered in the Office Action dated January 23, 2003.

Regarding claims 83-85, Applicants submit that no new search or consideration should be necessitated by the amendment of claims 83-85 because they encompass the composition recited in amended claim 30, and, as argued above, the full scope of amended claim 30 was previously searched and considered by the Office in the Office Action dated January 23, 2003.

In the absence of evidence that Applicants' amendment necessitated the new grounds for rejection, it appears that the new grounds for rejection resulted from the Examiner's new additional search and consideration conducted on his own initiative. This is further supported by the fact that the Examiners and Primary Examiners of record have changed from Examiner Robert DeWitty and Primary Examiner Jose Dees, on the January 23, 2003, Office Action, to Examiner Sharmila Gollamudi and Primary Examiner Michael Hartley in the current July 11, 2003, Office Action. Accordingly, the new grounds for rejection may have been the result of a different search and consideration process employed by the new Examiner and Primary Examiner.

While Applicants commend the Examiner's initiative to provide a thorough search and consideration of the claims, the evidence indicates that the new grounds for rejection were not necessitated by Applicants' amendment filed April 23, 2003. In accordance with the requirements of MPEP 707.07 (b) & (d), Applicants respectfully request reconsideration and withdrawal of the finality of the Office Action dated July 11, 2003.

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**II. The Claims Are Not Obvious Under 35 U.S.C. § 103**

The Office puts forth new grounds for rejection allegedly necessitated by the amendment filed on April 23, 2003. Claims 30, 33, 36, 41-50, 60-69, and 75-85 are rejected as allegedly obvious under 35 U.S.C. § 103. Office Action, pages 2-9.

Applicants respectfully traverse the rejections as follows.

**A. *Avalle***

***Avalle* by itself**

Claims 30, 33, 36, 41, 42, 46-50, 60-69, 75, and 79-85 were rejected under 35 U.S.C. § 103(a) as being obvious over *Avalle* (EP 0803245) ("*Avalle*").

To establish a prima facie case of obviousness, an Office must meet three basic criteria, including that, (1) the prior art reference must teach or suggest all the claim limitations and (2) there must be some motivation in the art to modify the reference. In the present case, the Office has failed to make a prima facie case of obviousness because at least these two criteria have not been met.

*Avalle* discloses a "compact-structure solid gel containing water." Col. 1, lines 3-4. *Avalle* states that the object of the gel is to have "solidity and compactness... without its form having to be compulsorily confined by a container during the application step." *Id.*, lines 14-20. *Avalle* then specifically states:

[T]he object [of the invention] has been attained with a gel characterized in that it contains the following ingredients:

- a) water in a concentration ranging from 15 to 90%;
- b) thermoreversible polysaccharides in a concentration ranging from 0.3% to 4%;
- c) humectant compounds in a concentration ranging from 4% to 40%;
- d) powder phase in a concentration ranging from 2 to 35%.

*Id.*, lines 21-32. *Avalle* defines "thermoreversible polysaccharides" to include

"carrageenin, agar, gellan..." *Id.*, lines 35-39. "Humectant compounds" as defined,

include “polypropylene glycol,...butylene glycol,...dipropylene glycol...” *Id.*, lines 40-44. “Powder phase” as defined, includes “excipients of traditional use in cosmetics such as mica, kaolin, talc,...zinc oxide,...spherical silicas,...iron oxides,...mica and titanium dioxide,...mica and bismuth oxychloride...” Col., lines 3-13. The independent claims of the present invention recite least one hydrophilic gelling agent (for example polysaccharides chosen from algal extracts, such as agar-agar, carrageenans, and alginates) and at least one pulverulent phase comprising at least one lamellar filler (for example talc, kaolin, mica, mica coated with silica beads, mica coated with titanium oxide, mica coated with bismuth oxychloride, coloured titanium mica, lamellar silica, lamellar titanium oxide, iron oxide, and zinc oxide.)

The Office admits that *Avalle* “does not specify the hardness of the [claimed] composition.” Office Action, page 3. The Office alleges, however, “it is deemed obvious to one of ordinary skill in the art to look to [*Avalle*] and formulate a gel with the instant hardness.” *Id.* The Office then asserts that *Avalle* “teaches a similar hardness due to the features recited above, which would cause the product to function as instant invention”. *Id.*

Applicants submit that the hardness value of *Avalle*’s gels does not inherently fall within the scope of the claimed compositions. Applicants point out that the Office’s de facto inherency argument is fundamentally flawed, e.g., there is no indication that *Avalle*’s compositions necessarily and inevitably exhibit the a hardness values falling within the range recited in Applicants’ claims. For example, since *Avalle* does not disclose any exemplary composition that anticipates Applicants’ compositions then there is no de facto evidence that the hardness of any of *Avalle*’s compositions is inherently the same as the hardness of any of Applicants’ compositions.

Further, Applicants point out that the indefinite components in the *Avalle*'s examples further support this argument. For example, in *Avalle*'s Examples 1, 2, and 3 some ingredients are only identified generically, such as polysaccharide, dimethicone copolyol, xanthane gum, carrageenin, sodium polymethacrylate, and Biosaccharide Gum-1. *Avalle* does not indicate the exact commercial product or exact chemical species used. These raw materials are only identified with a generic descriptive name that does not indicate, for example, the rate of synthetic polymerization or the molecular weight of the polymer used in *Avalle*'s specific examples. Accordingly, this further indicates that the Office's de facto inherency argument is fundamentally flawed, since there is no indication that *Avalle*'s indefinite compositions necessarily and inevitably exhibit the a hardness values falling within the range recited in Applicants' claims.

In addition, Applicants argue that there is no motivation to modify *Avalle*'s hardness range as suggested by the Office. The evidence of record provides no particular evidence or suggestion indicating that one of ordinary skill in the art would seek to modify the hardness of *Avalle*'s gels to devise Applicants' claimed invention. Without such guidance the claims cannot be obvious.

**Avalle in view of Roulier**

Claims 43-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Avalle* in view of Roulier *et al.* (US 6,045,814) ("*Roulier*"). Office Action, pages 3-4. The Office admits that *Avalle* "does not specify the particle size in the powder phase." *Id.*, page 4. *Roulier* discloses the use of "micas or aluminosilicates of varied compositions, which are in the form of flakes from 2 to 200  $\mu\text{m}$  in size..." Col. 4, lines 9-10.

Applicants traverse the rejection because the combination of *Avalle* and *Roulier* does not teach or suggest all of the limitations of the claims for the same reasons put

forth in response to the above §103 rejection over *Avalle* alone. Applicants submit that the hardness value of *Avalle*'s gels does not inherently fall within the scope of the claimed compositions. As discussed above, Applicants point out that the Office's de facto inherency argument is fundamentally flawed, e.g., there is no indication that *Avalle*'s compositions necessarily and inevitably exhibit the a hardness values falling within the range recited in Applicants' claims. Moreover, there is no evidence of record that the combination of *Avalle* and *Roulier* corrects this deficiency.

In addition, Applicants argue that there is no motivation to combine *Avalle* with *Roulier* to devise the claimed composition and hardness range as suggested by the Office. The evidence of record provides no particular evidence or suggestion indicating that one of ordinary skill in the art would seek to combine *Avalle* with *Roulier* to modify the hardness of *Avalle*'s gels to devise Applicants' claimed invention. Without such guidance the claims cannot be obvious.

**Avalle in view of Klein**

Claims 75-78 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Avalle* in view of Klein (US 4,486,405) ("*Klein*"). Office Action, pages 5-6. The Office admits that *Avalle* "does not specify the instant [claimed] surfactants." *Id.*, page 5. *Klein*, in combination with *Avalle*, allegedly teaches or suggests the surfactants recited in claims 75-78. *Id.*

Applicants traverse the rejection because the combination of *Avalle* and *Klein* does not teach or suggest all of the limitations of the claims for the same reasons put forth in response to the above §103 rejection over *Avalle* alone. Applicants submit that the hardness value of *Avalle*'s gels does not inherently fall within the scope of the claimed compositions. As discussed above, Applicants point out that the Office's

de facto inherency argument is fundamentally flawed, e.g., there is no indication that *Avalle*'s compositions necessarily and inevitably exhibit the a hardness values falling within the range recited in Applicants' claims. Moreover, there is no evidence of record that the combination of *Avalle* and *Klein* corrects this deficiency.

In addition, Applicants argue that there is no motivation to combine *Avalle* with *Klein* to devise the claimed composition and hardness range as suggested by the Office. The evidence of record provides no particular evidence or suggestion indicating that one of ordinary skill in the art would seek to combine *Avalle* with *Klein* to modify the hardness of *Avalle*'s gels to devise Applicants' claimed invention. Without such guidance the claims cannot be obvious.

**B. Roulier**

Claims 30, 33, 36, 41, 43-50, 60, 63-66, 68, 69, and 79-85 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Roulier* by itself, or further in view of Miyajima (US 5,891,450) ("*Miyajima*"). Office Action, pages 6-7.

In order to establish a prima facie case of obviousness the Office must meet three criteria: (1) the combination of references must teach or suggest all of the recited claim limitations, (2) there must be motivation to make the modification or combination suggested, and (3) there must be a reasonable likelihood of success. Applicants traverse these remaining rejections because none of these criteria have been met.

The Office admits that *Roulier* "does not teach the gelling agent in the instant [claimed] amount." *Id.*, page 6. For example, *Roulier* specifically discloses "gels containing at least 20% by weight...hydrophobic gelling agent(s)..." Abstract. Also, "Applicant has discovered, unexpectedly, that

homogeneous, stable, rigid sticks, whose gelled matrix may contain more than 20% by weight of water soluble gelling agent...can be produced... ." Col. 2, lines 8-12. "The compositions according to the invention are rigid gels containing...at least 20% by weight of at least one...hydrophilic gelling agent... ." *Id.*, lines 50-54.

The Office, however, alleges:

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the amount of hydrophilic gelling agent utilized in *Roulier et al.* since the instant claims merely recite "less than 20%" and *Roulier* teaches a preferable range of 20-80%. Therefore, the inclusion of the gelling agent in the amount of 19.95%, for example, does not impart patentability to the claims. The mere optimization of ranges through routine experimentation of concentration does not support patentability unless evidence indicating criticality is provided.

*Id.*, emphasis added.

**Roulier by itself**

First, Applicants argue that reducing the concentration of hydrophilic gelling agent to "less than 20%" would not constitute a matter of routine skill, particularly in view of *Roulier's* guidance that:

The production of sticks whose matrix consists of an aqueous gelled network, of sufficiently high rigidity, requires the presence of at least one water-soluble gelling agent in high concentrations, generally greater than 20% by weight. Hitherto, it was not possible to manufacture such solid aqueous gels by the conventional techniques such as manufacture by casting.

Col. 2, lines 1-7. This is further supported by Applicants' own specification:

[M]ake-up products are generally formulated on the basis...of a fatty phase for reasons of comfort and softness.... The fatty phase generally comprises waxes...which give the sticks structure.

However, sticks formulated with a wax base have certain drawbacks: they have a greasy nature which users do not find appealing and they lack freshness when applied. In addition, it is difficult to introduce hydrophilic active agents therein.



It is therefore increasingly being sought to make make-up sticks comprising an aqueous phase in the highest concentration possible. However, sticks comprising a large aqueous phase are occasionally subject to problems of stability and lack of cohesion. In particular, these gels, which are made from a combination of a hydrophilic gelling agent and water, have the drawback of being fragile and of breaking easily during use.

One means for improving the gel strength is to increase the concentration of hydrophilic gelling agent, but the gels then become difficult to disintegrate, i.e. the amount of material lifted during uptake of the product is insufficient.

Page 1, line 22, to page 2, line 21, emphasis added.

Second, Applicants point out that a “particular parameter must first be recognized as a result-effective variable... before determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” MPEP § 2144.05 II.B.; *In re Antonie*. Because *Roulier* is silent on whether the hydrophilic gelling agent, or any other variable component, results in a rigid gel of defined hardness, *Roulier* by itself fails to show the requisite recognition of hydrophilic gelling agent concentration as a result-effective variable. Thus, a rejection based on routine experimentation to achieve suitable hydrophilic gelling agent concentration in view of *Roulier* is improper.

Third, Applicants point out that there is no motivation to make the modification suggested by the Office. In particular, there is no evidence of record to indicate that one of ordinary skill in the art would seek to decrease the concentration of *Roulier*’s hydrophilic gelling agent to a concentration of less than 20% by weight. For example, *Roulier*’s compositions provide for rigid gels “...whose matrix consists of an aqueous gelled network, of sufficiently high rigidity, requires the presence of at least one water-soluble gelling agent in high concentrations, generally greater that 20% by weight....” Col. 2, lines 1-7.

Finally, there is no evidence of record to indicate that one of ordinary skill in the art at the time of invention would have had a reasonable likelihood of success of modifying *Roulier* to attain the claimed invention. Applicants' own specification provides the only indication that the claimed compositions could be attained with a reasonable likelihood of success.

**Roulier in view of Miyajima**

The Office alleges:

*Miyajima* discloses that cellulose ethers are relatively excellent in viscosity stabilizing ability in aqueous solutions compared with Carbopol but are lower in thickening ability in the same concentration. Therefore it is necessary to increase the amount of cellulose ethers to provide the same thickening ability. [*Miyajima's*] polysaccharide is novel in that it has excellent transparency and thickening ability at low concentrations.

Office Action, page 6. The Office then concludes it would have been obvious to combine the teachings of *Roulier* and *Miyajima* and incorporate the gelling agent in the instant amount. "One would have been motivated to do so since *Miyajima* teaches that gelling agent/thickener has different properties and depending on its concentration, increases the viscosity of the composition to the desired consistency." *Id.*, page 7. Applicants disagree for the following reasons.

First, *Miyajima's* teaches that for cellulose ethers commonly used in cosmetics that "it is necessary to increase the amount of cellulose ethers to provide the same thickening ability." Col. 1, 37-40. This is clear and particular evidence that one of ordinary skill in the art would not decrease the concentration of *Roulier's* gelling agent to less than 20% by weight to attain a rigid gel.

Second, *Miyajima's* polysaccharide, has been derivatized to include two substituents uncharacteristic of most polysaccharides: (A) a hydrophobic group

containing a linear or branched alkyl, alkenyl or acyl group having 10-40 carbon atoms; and (B) a sulfoalkyl group having 1-5 carbon atoms, which may be substituted by a hydroxyl group, or a salt thereof, and further requiring an average degree of substitution of (A) and (B). Col. 2, lines 34-48. *Miyajima's* particular derivative exhibits high thickening at low concentrations. Col. 2, lines 10-33. *Miyajima* attained higher thickening at lower concentrations of polysaccharides by replacing the polysaccharide with a polysaccharide derivative having particular chemical substituents. *Miyajima* did not attain higher thickening at lower concentrations of polysaccharides by merely optimizing the concentrations of various components. Accordingly, there is nothing in *Miyajima* that teaches or suggests modifying the concentration of *Roulier's* gelling agent to attain the claimed invention.

Third, as discussed above, a "particular parameter must first be recognized as a result-effective variable... before determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." MPEP § 2144.05 II.B.; *In re Antonie*. The Office asserts that "*Miyajima* teaches that gelling agent/thickener has different properties and depending on its concentration, increases the viscosity of the composition to the desired consistency teaches or suggests that differences in the concentration of polysaccharide in a composition, such as hydrophilic gelling agent, results in differences in composition viscosity." Office Action, page 7.

*Miyajima* taken as a whole, however, identifies multiple variables that may play a role in how *Miyajima's* polysaccharide derivative modifies the viscosity of a composition. For example, the variables could include (A) substituting hydrogen atoms of hydroxyl groups with alkyl, alkenyl or acyl groups having 10-40 carbon atoms; (B) the presence of sulfoalkyl groups having 1-5 carbon atoms; and the average degree of substitution of

(A) and (B) on the polysaccharide. Accordingly, *Miyajima* would appear to suggest that a polysaccharide's substituents A and B might be useful as result-effective variables for determining optimum viscosity and solubility ranges. In the present application, however, there is no evidence of record to indicate that characterization of polysaccharides on the basis of whether they have substituents A and B would lead one of ordinary skill in the art to modify the concentration of *Roulier*'s gelling agent to be less than 20% by weight.

Finally, Applicants point out that there is no motivation to make combine the references cited by the Office. For example, *Miyamata* teaches certain polysaccharides that are specifically modified with substituents A and B, and how they provide superior solubility and viscosity characteristics as compared to polysaccharides conventionally used in cosmetics. Accordingly, *Miyamata* appears to teach away from the use of conventional polysaccharides, such as those recited in the present claims.

**Roulier in view of Miyajima and in further view of Avelle**

Claims 61-63 and 67 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Roulier* in view of *Miyajima* in further view of *Avelle*. Applicants traverse this rejection for the same reasons given above for traversing *Roulier* in view of *Miyajima*, and incorporate those arguments herein by reference. Applicants further point out that the addition of *Avelle* to the combination of references does not correct these deficiencies.

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**CONCLUSION**

Applicants therefore respectfully request reconsideration of the application, withdrawal of the finality of the July 11, 2003, Office Action, and the timely allowance of the pending claims. Please grant any extensions of time required to enter this amendment and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: November 12, 2003

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